THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 15

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JEFFRY W. KREAMER

Appeal No. 95-4911
Application 08/071,052[1]

ON BRIEF

Before WEIFFENBACH, PAK, and WALTZ, *Administrative Patent Judges*.

WEIFFENBACH, *Administrative Patent Judge*.

REMAND TO THE EXAMINER

For the reasons set forth below, we hereby vacate the examiner's final rejection and remand this application to the jurisdiction of the examiner for further consideration.

The examiner objected to the specification arguing that "the proportions of active agents present in the synergistic compositions are not clearly set forth in the specification" and rejected

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[1] Application for patent filed June 4, 1993.

claims 11-26 under 35 U.S.C. § 112, first paragraph, for this reason. Then the examiner argued that claims 11-26 "fail to recite the active agents or the ratio of active agents which will yield the synergistic effect" and that the "claims are not commensurate in scope with the data which applicant argues shows a synergistic activity" (answer: p. 3). These arguments appear to be separate and apart from the aforementioned rejection, but the examiner did not make a separate rejection of the claims based on these arguments. It is not clear to us whether the examiner intended these separate arguments to be part of the rejection under the first paragraph of 35 U.S.C. § 112 or whether the examiner intended these arguments to be a separate rejection to which the examiner failed to cite a statutory ground.

The examiner did not indicate whether the rejection under 35 U.S.C. § 112 was based on lack of enablement or lack of written description. To the extent the examiner may have relied on the enablement requirement of the first paragraph of 35 U.S.C. § 112, we observe that the examiner has failed to present any evidence or arguments indicating that one of ordinary skill in the art would require undue experimentation to make and use the claimed invention. *United States v. Telectronics. Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1222-3 (Fed. Cir. 1988); *In re Stephens*, 529 F.2d 1343, 1345, 188 USPQ 659, 661 (CCPA 1976). The written description requirement is separate and apart from the enablement, how to make and how to use, requirement. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991); *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984), *cert. denied, sub nom. Wilder v. Mossinghoff*, 469 U.S. 1209

(1985); *In re Barker*, 559 F.2d 588, 591, 194 USPQ 470, 472 (CCPA 1977), *cert. denied, sub nom, Barker v. Parker*, 434 U.S. 1238 (1978). The written description requirement is met if the description in the specification clearly allows persons of ordinary skill in the art to recognize that the inventor invented what is claimed. *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). The examiner has not presented any evidence on this record that a person having ordinary skill in the art would not have found that the inventor had possession of, as of the filing date of the application relied on, the specific subject matter which is now claimed, i.e., a method of reducing arteriosclerotic plaque formation by the oral administration of aspirin and a medicament. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

The examiner's arguments for the 35 U.S.C. § 112 rejection appear to be directed to the sufficiency of appellant's evidence to establish synergism. The insufficiency of such evidence is not a basis for a rejection under 35 U.S.C. § 112, first paragraph, but is a matter to be taken into consideration in determining whether the claims would have been obviousness under 35 U.S.C. § 103.

Accordingly, for the foregoing reasons, the examiner should reconsider the rejection of the claims under 35 U.S.C. § 112, first paragraph.

The examiner rejected claims 11-26 under 35 U.S.C. § 103 as being unpatentable over Igarashi et al. (U.S. Patent No. 4,088,778) , Fratzer (U.S. Patent No. 4,874,603), and Frisbee (U.S. Patent No. 4,970,081). Claim 11 recites a method of orally administering a dosage of aspirin for

blocking prostaglandin function in platelets and orally administering a medicament for reducing the migration of cholesterol into the endothelium. Claims 12-17 which are dependent on claim 11 specify the medicament as being niacin or a vitamin such as vitamin A, vitamin C, vitamin B_6 and vitamin E. Claims 19-26 are dependent on claim 11 and specify the medicament as being a trace element such as chromium, copper, magnesium, selenium and zinc. Igarashi discloses orally administering a vitamin E derivative to treat hypertension (col. 1, 7-10; col. 2, lines 18-20; col. 6, lines 10-12) while Fratzer discloses orally administering vitamin E to normalize blood coagulation (abstract; col. 3, lines 54-57). Frisbee teaches that aspirin significantly decreases platelet adhesiveness to vascular walls (col. 1, lines 25-37). Frisbee's invention is directed to a formulation for a slow-release aspirin.

None of the references relied upon by the examiner disclose or suggest the concept of administering aspirin and a medicament such as a vitamin or a trace element. However, we note that appellant relies on the data summarized in Table 3 of the specification to show the alleged synergistic effect. According to appellant, "Table 3 summarizes the results of an unpublished observational study conducted by the University of Southern California ..." (specification: p.. 14). The data appears to show that the concept of combining aspirin and a multivitamin was known to a party other than the inventor at the time the application was filed. While appellant states that the data is unpublished, the data could represent prior art under 35 U.S.C. §§ 102(a) and/or 102(f). Also, the declaration by Larry H. Hollier, MD (paper no. 5 and attachment 7 of the brief)

acknowledges that multivitamins are the most typical type of over-the-counter vitamins taken by the general public and that such vitamins are typically administered in tablet form and typically contain the trace elements claimed by appellant (declaration: ¶¶ 12-13). Moreover, on page 6 of the specification, appellant states that "[a]spirin is an anti-inflammatory agent which is known in the art to irreversibly block platelet protaglandin [sic, prostaglandin] function." Appellant further acknowledges that it is within the skill of the art to orally administer dosages of aspirin to block prostaglandin function in platelets and to orally administer dosages of minerals or vitamins to reduce the migration of cholesterol into the endothelium, and that the amounts of such dosages are well known in the art (specification: p.. 2-4, 6-12; brief: p. 6).[2] In addition, the specification is replete with citations to published research of others to demonstrate the properties summarized in Tables 1 and 2 of appellant's specification (see pp. 1-12).

Accordingly, with respect to claims 11-17 and 19-26, the examiner should consider the following in determining the patentability of the claimed subject matter under 35 U.S.C. §§ 102 and/or 103:

1. The examiner shall determine the metes and bounds of claim 11 keeping in mind that the claims are given the broadest reasonable interpretation consistent with the specification and that the claims are interpreted in light of the specification as it would be interpreted by one of ordinary skill

[2]The amount of aspirin and the vitamin or trace element administered would be variables. Optimization of such variables in a combined dosage may be recognized in the prior art to be a result effective variable would ordinarily have been within the skill in the art. *In re Boesch*, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980).

in this art. *In re Morris,* 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997); *In re Zletz,* 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

2. The examiner shall determine the scope of appellant's admission or acknowledged state of the art taking into consideration appellant's brief and responses to rejections, statements in the specification summarizing the research of others, and the Hollier declaration. *In re Nomiya*, 509 F.2d 566, 570-71, 184 USPQ 607, 611 (CCPA 1975). The examiner shall also determine if the data in Table 3 of the specification is prior art under 35 U.S.C. § 102(a) and/or 102(f) for the concept of combining aspirin and vitamins, and/or is acknowledged prior art by appellant.

3. The examiner shall consider taking official notice of the fact that humans take aspirin and vitamin supplements by oral administration and that it is not be uncommon that aspirin and vitamin supplements are taken together. If the examiner concludes that official notice should be taken of such facts, the examiner shall explain the reasons for his or her conclusion.

4. The examiner shall determine the patentability of claims 11-17 and 19-26 in view of the determinations made in accordance with items 1-3, *supra*, as applied in *Graham v. Deere*, 148 USPQ 459, i.e., making a factual inquiry into (1) the differences between the claimed subject matter and the prior art; and (2) whether the differences are such that the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the invention was made. If the examiner determines that the claims are unpatentable, then the examiner shall set forth detailed reasons for determining obviousness and explain why appellant's showing of synergism is

inadequate. In considering the adequacy of the showing, the examiner shall determine whether the showing is within the scope of the claimed subject matter.

As for claim 18, this claim is an independent claim which appears to be directed to a method of reducing arteriosclerotic plaque formation by orally administration of vitamin E only. The examiner shall consider whether this claim is anticipated under 35 U.S.C. § 102(b) by Igarashi and/or Fratzer who disclose the oral administration of vitamin E. The examiner shall consider also the patentability of claim 18 over the numerous admitted teachings in the prior art set forth in appellant's specification with regard to vitamin E. The examiner shall determine also the metes and bounds of claim 18 and determine whether a person having ordinary skill in the art would have considered claim 18 as being subject matter which the inventor had in his possession as of the filing date of the application relied on, i.e. the administration of vitamin E only. We note that this claim recites "through the oral administration of vitamin E as said medicament." Because the term "said medicament" does not have antecedent basis in the claim, the examiner shall further consider rejecting this claim under 35 U.S.C. § 112, second paragraph.

For the forgoing reasons, the examiner's final rejection is vacated and this application is remanded to the jurisdiction of the examiner for further consideration of the patentability of the claimed subject matter.

This application, by virtue of its "special" status, requires immediate action by the examiner, M.P.E.P § 708.01(d). It is important that the Baord be informed promptly of any action which may be taken which affects the appeal in this case.

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